

REMARKS

This reply is being entered in response to the Office Action of April 12, 2005. In this Office Action, the Examiner made the following objections and rejections:

- 5 1. Rejection of claim 13 as allegedly non-statutory under 35 USC 101.
2. Rejection of claims 1-13, 18-20 and 22-23 as allegedly obvious under 35 USC 103.

10 The applicant has amended claim 1 to recite at least one limitation not found or suggested in the prior art of record. Arguments addressing the alleged obviousness of the claims are also presented. Reconsideration is respectfully requested.

1. Rejection of claim 13 as allegedly non-statutory under 35 USC 101.

15 The Examiner has rejected claim 13 as allegedly being drawn to non-statutory subject matter under 35 USC 101, stating:

20 Claim 13 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. Claim 13 appears to include parts of a human body as surfaces in between the thermocouple surfaces. Inclusion of human body parts in claim language is not permitted under 35 USC 101.

25 Applicant has studied claim 13 at great length, but it is unclear how the Examiner determined that a human body part is being presented as a limitation in claim 13. Applicant has theorized that the Examiner intended to refer to claim 1, and has amended claim 1 to clarify the invention. Claim 1 has been amended to include the phrase "adapted to be." As such, it is now clear that the recited limitation, "disposed in a living organism," is a property of the device, and is not
30 claiming part of the living organism itself. It is respectfully submitted that the rejection of claim 13 under 35 USC 101 has been obviated.

2. Rejection of claims 1-13, 18-20 and 22-23 as allegedly obvious under 35 USC 103.

The Examiner has rejected claim 1-13, 18-20 and 22-23 as allegedly obvious under 35 USC 103 in view of United States patent 6,470,212 to Weijand, in view of United States patent 6,108,579 to Snell, in further view of United States patent 6,067,473 to Greeninger, stating:

Weijand teaches a thermoelectric charging assembly having thermocouple 252 with temperature sensors 262 and 264, a DC-DC converter and a control element 260 that provide [sic] means for transferring thermal energy (sensor 262, 264), means for generating electrical current, means for charging an electrical storage device (256) as well as lines positioned between the charging assembly and storage element (between 254 and 256) and lines between the storage element (256) and the implantable device circuitry 258. The storage device may be a battery or a capacitor (column 13, lines 47-49) and the implant device may be used for delivering drugs, stimulating nerves (would include nerves in brain) or regulating cardiac activity. The Examiner considers the elements 262 and 264 to be the sensors since nothing in the claim indicates that they are different from the means for transferring energy, the device can be used for regulating heart rate, which in turn may regulate body temperature since a more rapidly beating heart burns more calories and transfers heat to the body through the circulatory system. Applicant's power ratings are well known (applicant is using convention constructs in the specification) and the values would be recognized as useful in the implant art. The examiner considers the implant assembly of Weijand to lie on an open table and may be "proximate" (noted relative term) to heating elements such as heaters in a physician office that are outside of the range of temperatures between the sensors.

Applicant differs in reciting a means for detecting battery charge and a means for indicating the current is low. Applicant's specification indicates that his means are those of Snell et al. and Greeninger et al. Similarly, the examiner considers it obvious to incorporate these elements into the Weijand et al

device, since knowing the current level/ [sic] battery state is crucial to sustaining life of those relying upon the Weijand et al pacing device. To have include [sic] such features in the Weijand et al device would have been a modification considered obvious to one of ordinary skill for their disclosed advantages.

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With respect to claim 1, the Examiner has acknowledged Weijand does not teach either a (1) means for determining the extent to which the electrical storage device is being charged and (2) means for generating a signal whenever the storage device's charge falls below a specified value. The Examiner then asserted that Snell teaches the means for determining the charge of the storage device and that Greeninger teaches the means for generating the signal. The Examiner asserted that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Weiland, Snell, and Greeninger to arrive at the applicant's claimed invention. It is respectfully submitted that such a combination is impermissible, as the only motivation to perform such a combination is in the applicant's specification itself.

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For a rejection under 35 USC 103 to be tenable, the references must provide a suggestion or motivation to combine the cited references. MPEP § 2143 states:

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To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations). The teachings or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure. In re Vaeck, 947, F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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Applicant respectfully submits that the mere fact that prior art may be modified is not enough to make such modification obvious without more. The

Supreme Court's decision in *Graham v. John Deere Co.* set forth the required factual analysis required to support a claim that the prior art suggested the claimed invention. MPEP § 2141; 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Conspicuously lacking any support or reference to a motivation to combine in the prior art disclosure, applicant must assume that the reader was first motivated to refer to the teachings of Snell and Greeninger by the applicant's specification. Applicant respectfully submits that the Examiner relied upon hindsight to arrive at his determination of obviousness, impermissibly using the claimed invention as a template to piece together teachings of prior art so that the claimed invention was rendered obvious. See *In re Fritch*, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988).

The Examiner stated "Applicant's specification indicates that his means are those of Snell et al. and Greeninger et al." The Examiner then concluded that it would have been obvious to one of ordinary skill in the art to combine the cited references. The question before the Examiner is "But for the applicant's own specification, would one of ordinary skill in the art be motivated to make the present modification(s)?" The applicant respectfully submits that the Examiner has failed to provide such a suggestion or motivation. Absent such a suggestion or motivation, a rejection under 35 USC 103 is improper and should be withdrawn. MPEP § 2143; *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988).

Applicant would also like to note that claim 1 has been amended to recite the limitation of producing at least 50 mW of power when exposed to a temperature differential of 2 degrees Celsius. For reasons that will be discussed elsewhere in this amendment, it is clear that the prior art of record does not teach or suggest a device with such a power output. As such, claim 1 should be allowed in view of the prior art of record.

With regard to claims 2-6, the applicant notes that such claims depend, either directly or indirectly, upon claim 1. As such, if claim 1 is allowable, then the dependent claims are likewise allowable.

With regard to claims 7 and 8, the Examiner has stated:

5 The examiner considers the the [sic] elements 262
 and 264 to be the sensors since nothing in the claim
 indicates that they are different from the means for
 transferring energy...

10 The Applicant would like to take this opportunity to address the Examiner's
 question and clarify the difference between a sensor and a means for transferring
 energy. The applicant respectfully disagrees that there is nothing in the claims to
 indicate that the sensors are different from the means for transferring energy.
 Applicant notes that both claims 7 and 8 recite the transitional phrase "further
 comprising" which clearly indicates the addition of a new limitation that was not
 present in the base claim. Reference may be had to page 12, beginning at line
15 18, which states:

20 Referring again to Figure 1, a temperature sensor 41
 senses the temperature outside the living organism,
 preferably at or through the surface of the organism's
 skin. This information is conveyed, via lines 43, to
 power monitor 30.
 A second temperature sensor, sensor 45, senses the
 temperature of the living organism and provides such
 information, via lines 47, to the power monitor 30.
25 Thus, at all times, the power monitor can determine
 the difference between the temperature on surfaces
 42 and 44, the direction of such temperature
 difference, and the amount of time such temperature
 difference has existed.

30 It is clear from the above paragraph and from Figure 1 of the drawings as
 filed that the first and second sensors are separate and distinct from the means
 for transferring energy. It is respectfully submitted that the Examiner's questions
 concerning claims 7 and 8 have been addressed.

35 With regard to claims 9 and 10, the applicant notes that claims 9 and 10
 each recite a specific power output of the thermoelectric charging assembly.
 Applicant notes that the Examiner simply asserted that the "...power ratings are
 well known...and the values would be recognized as useful in the implant art,"

but the Examiner did not provide a reference supporting such an assertion. Such a rejection is improper. MPEP § 2144.03 states:

...ordinarily, there must be some form of evidence in the record to support an assertion of common knowledge. See Lee, 277 F.3d at 1344-45, 61 USPQ2d at 1434-35 (Fed. Circ. 2002); Zurko, 258 F.3d at 1386, 59, USPQ2d at 1697 (holding that general conclusions concerning what is 'basic knowledge' or 'common sense' to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these will not support an obviousness rejection.

Applicant respectfully submits that the Examiner did not specifically cite to prior art references or reference works recognized as standard in the pertinent art in suggesting these technical arguments, relying instead on his own personal knowledge. Whereas the Examiner is an expert in his technical field, his knowledge does not represent the knowledge of one with ordinary skill in the art.

Applicant also notes that the prior art of record does not teach or suggest, and furthermore cannot teach or suggest, the recited power output ranges. Specifically, applicant notes that the device of Weijland does not teach the power recited in either claim 9 or claim 10. As is well known to one skilled in the art, the Seebeck effect relies upon heat flowing from a first location to a second location. Given the teachings of Weijland (beginning at column 12, line 54) it is clear that Weijland's thermocouples cannot generate at least 50 microwatts of power given a one degree temperature differential, as recited by the instant claims. In contrast, the configuration of the applicant's invention generates substantially more power than the Weijland device.

Weijland teaches placing thermocouples 262 and 264 at distant locations with leads electrically connecting the thermocouples. As would be apparent to one skilled in the art, thermocouples, by design, generate minute voltages in response to temperature differentials. Typical values for voltages produced by thermocouples are as follows:

Thermocouple composition	Voltage produced (mV/C)
Iron/Constantan	0.06 mV/°C
Chromel / Alumel	0.04 mV/°C
Platinum/Platinum-10% Thodium	0.01 mV/°C
FeCu/NiCr	0.05 mV/°C

While it may be true that the thermocouples of Weijland generate some degree of power (see the chart above), it is clear that the resulting power is nowhere near that recited in claims 9 or 10. Even theoretically, the device of Weijland cannot produce the recited power output.

WEIJLAND DOES NOT TEACH, EVEN IN THEORY, THE RECITED POWER OUTPUT

The device of Weijland cannot, even in theory, produce the power output recited in the present claims. As would be apparent to one skilled in the art, the efficiency of the Seebeck effect is dependent upon the materials used to create said effect. Such materials may be typical thermal couple materials (see above) or so called "quantum well materials." At best, "quantum well materials" perform the thermoelectric conversion with 2.5% efficiency. Reference may be had to "Quantum Well Thermoelectric Devices" by Elsner et al. in the December 2003 issue of MRS, a copy of which is attached for the Examiner's reference. Typical thermocouple materials perform the conversion with much lower efficiency. For the sake of argument, the applicant has assumed that the device of Weijland behaves at a quantum well material, and therefore has the maximum efficiency of 2.5%. Even though such an assumption is not taught in Weijland, applicant has elected to make such an assumption for the purposes of this argument.

Given the assumed 2.5% efficient, for the device of Weijland to produce 50 μ W of electrical energy as recited in claim 9, at least about 0.002 W must be produced. Reference may be had to equation 1:

Equation 1

$$\left(\frac{50 \mu\text{W}}{2.5\%} \right) \left(\frac{W}{10^6 \mu\text{W}} \right) = 0.002 \text{ W}$$

This corresponds to a temperature difference between the thermocouples of 3.6 °F. The same temperature differential exists between the core temperature (approximately 37.0 °C) and skin temperature (approximately 32-35 °C). Reference may be made to the attached copy of an article by Freitas, entitled "Nanomedicine, Volume I: Basic Capabilities."

If one further assumes that Weijland uses an ideal conductor (i.e. copper wire) with typical thermocouple dimension (0.02 inches in diameter (0.0000022 ft²), 1.67 feet long (similar to the pacing lead in a pacemaker, as taught by Weijland), and if one further assumes that the copper conductor was insulated in a perfectly insulated material, the aforementioned temperature difference of 3.6 °F would result in only 0.000007 W of heat flow, not the requisite 0.002W.

Equation 2

$$Q = \frac{kA(T_2 - T_1)}{L}$$

Where: k for copper is 200 BTU ft/ F
A is wire cross-section (0.0000022 ft²)
L is wire length (1.67 ft)
(T₂ – T₁) is 3.6 °F

From the above equation it can be determined that Q is 0.00095 BTU/hr or 0.00028 watts of heat conducted by the wire. At 2.5% efficiency this creates only 7 uW (0.000007 W) of electrical power, which is approximately one thousand times less than that recited in the present claims.

The foregoing assumes the device of Weijland has a perfect thermal isolation of the copper conductor from the surrounding tissues as it moves from the cold junction to the hot junction. It is therefore clear that, even in theory, the device of Weijland cannot produce the recited heat flow. Such theoretical

assumptions are unrealistic and the real device is expected deviate from this idealized situation significantly.

WEIJLAND DOES NOT TEACH, IN PRACTICE, THE RECITED POWER
5 OUTPUT

The real device would need to avoid shifting the actual temperature of the conductor as compared to its theoretically perfect value by more than a very small amount. Again favoring Weijland, the following calculations assume a 20% section of the length of the copper wire will not effect a change from the ideal
10 temperature condition of more than 10%. The following calculations further assume the copper wire is covered in an insulating jacket with typical insulating properties. Conductivity for such insulating jackets is typically around 0.08 BTU ft/ F, and some expanded foam jackets may run as low as 0.02 BTU ft/ F, albeit not structurally appropriate to this application. In a good faith effort to place the
15 invention of Weijland in its best possible like, a value of 0.05 BTU ft/ F will be used.

Again, Equation 2 may be used.

Equation 2

$$Q = \frac{kA(T_2 - T_1)}{L}$$

20 The following calculations compare the relative thermal resistance of the conductor along its length, to the thermal resistance of the insulating jacket normal to its length (assuming thickness of jacket is a typical 0.0025 ft).

For the wire:

k for copper is 200 BTU ft/ F

25 L = 0.33 ft (20% of 1.67 ft)

A = 0.0000022 ft²

(T₂ - T₁) is 0.72 F (20% of 3.6 °F, and the condition required for operation at the 50 μW power level)

Result: 0.00095 BTU/hr

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For the jacket:

k for an insulating jacket is 0.05 BTU ft/ F

$L = 0.0025$ ft (heat flowing normal to the lead)

$A = 0.052$ ft² (heat flowing normal to the lead)

5 $(T_2 - T_1)$ is 3.2 °F (80% of 3.6 °F, representing the difference between the mean temperature of the conductor and the tissue in this location, assuming a linear change along conductor length)

Result: 3.33 BTU/hr

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The ratio of heat flow transverse to the conductor (effectively shunting it thermally and defeating its purpose as stated by Weijland) of 3.33 BTU/hr, to the heat flow along the conductor of 0.00095 BTU/hr, is a factor of 3400. This ratio clearly shows the practical application of the device will perform over three
15 thousand times worse than the theoretical application. As the theoretical application does not produce the claimed power output, the practical application cannot produce the claimed value. Thus with real-world material and design constraints, the previously calculated value of 7 uW is utterly unattainable, either in theory, or in application, given the teachings by Weijland.

20 Clearly, in this highly idealized situation, Weijland's device still has a power output that is several orders of magnitude too low to produce the power recited in the present claims. Weijland simply does not teach how to generate the recited power output.

25 The present invention is distinguished from the teachings of Weijland by the configuration of the means for generating an electrical current. The elements of such a configuration are recited in newly presented claim 38.

As recited in the specification as filed (see, for example, the Figure 4 of as filed and the associated description) the thermoelectric assembly is comprised of a first and second surface. These surfaces are disposed substantially parallel to
30 one another and, in one embodiment, substantially parallel to skin surface 92. In this manner, a greater degree of surface area is available to perform heat

exchange. Applicant notes that none of the prior art of record teaches such a thermoelectric configuration, nor does the art of record contain a suggestion or motivation to include such a configuration. Absent such a teaching, it is respectfully submitted that the newly presented claims are patentable in view of the prior art of record.

With regard to claim 11, the Examiner has asserted that the limitation of "means for increasing said temperature of said living organism" is taught by Weijland. In so doing, the Examiner claimed that increasing the heart rate of the living organism serves as a means to increase the temperature of the living organism. Applicant respectfully disagrees.

Firstly, Weijland does not teach adjusting the heart rate of the patient so as to increase the temperature of the patient. If the prior art of record does not teach all of the limitations, then a rejection under 35 USC 103 is improper. Reference may be had to MPEP § 2143 which states "Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations)." At best, Weijland teaches regulating the heart rate so as to maintain normal physiological temperature of the patient. The limitation recited in the claim is simply not present in the prior art of record.

Secondly, if the invention were modified such that Weijland's device did increase heart rate so as to increase body temperature, then such a modification would render the pacemaker unsatisfactory for its intended purpose. MPEP § 2143.01 states :

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Circ. 1984)

The applicant notes that patients who have pacemakers implanted would likely not wish to have their heart rate increased; that's why they have the pacemaker. The aforementioned patients would certain not want their heart rates increased to such a degree that it increases their body temperature, as

such a quickened heart rate increases the likelihood of a heart attack; presumably what the pacemaker was designed to prevent.

5 With regard to claim 12, the Examiner has not even asserted that the limitation of "a means for applying a stimulus to the tissue of said living organism" is taught in the prior art. In order to sustain an obviousness rejection, the Examiner must show that the combination of prior art references teaches all of the claim limitations. Having failed to establish even one claim limitation renders the obviousness rejection *prima facie* improper.

10 It is unclear if the Examiner intended this limitation to be covered under the previous claim 11 rejection. Applicants have amended claim 12 in an earnest attempt to address the rejection. The applicant has amended claim 12 to recite that the stimulus is a chemical irritant. Reference may be had to the specification as filed. For example, see page 22, at line 6 which states:

15 In various embodiments, the method is performed manually or automatically by electrical stimulation of tissue, performed manually by the living body (i.e. the person or "patient") in which the device is implanted or by another person, or
20 performed manually or automatically by chemical stimulation (irritation) of tissue.

Regarding claim 13, the Examiner has asserted that the thermally conductive member may be, for example, a heating element in a physician's office and noted that the term "proximate" may be a relative term.

25 The claim at issue recites the limitations of a "first surface," "second surface," and "thermally conductive member" and the relationships between the aforementioned limitations. It appears that the Examiner is drawing a correlation between the "thermally conductive member" and the "heating element in a physician's office." The applicant notes that none of the prior art of record
30 teaches or suggests such a thermally conductive member.

The Examiner has failed to provide a reference that teaches the use of a thermally conductive member. It appears that the Examiner has instead relied upon supposed "common knowledge." As already discussed elsewhere in this

specification, it is improper to reject a claim based on such supposed "common knowledge" without providing some form of evidence in the record. Reference may be had to MPEP § 2144.03 that was recited elsewhere in this amendment.

While the applicant contends that the rejection is improper, the applicant has amended the claims so as to recite the limitation that the thermally conductive member is contiguous with the first or second surface. Examples of such a configuration may be found in the specification as filed. Reference may be had to Figure 5 (thermally conductive member 96 and surface of module 12); Figure 6 (thermally conductive member 114 and surface of module 12), and the like.

Applicant notes that the prior art of record does not teach or suggest the use of thermally conductive members that are contiguous with the first and second surfaces as recited in the present claims. Moreover, applicant also notes that the prior art of record does not contain a suggestion or motivation to include such a limitation. Absent such a teaching and/or a suggestion to include such a teaching, a rejection of claim 13 under 35 USC 103 is improper and should be withdrawn.

With regard to claims 18-24, applicant would like to note that claim 18 has been amended to recite the limitation of producing at least 50 mW of water when exposed to a temperature differential of 2 degrees Celsius. For reasons that have been discussed elsewhere in this amendment, it is clear that the prior art of record does not teach or suggest a device with such a power output. As such, claim 18, and its dependents, should be allowed in view of the prior art of record.

With respect to claims 21 and 24, the Examiner has further stated:

Claims 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weijand et al USPN 6,470,212 in view of Snell et al. USPN 6,108,579 or Greeninger et al USPN 6,067,473 as applied to claims 1-13, 18-20, 22-23 above, and further in view of Leysieffer USPN 6,269,266. Applicant differs from the combinations of Weijand et al in view of either Snell et al. or Greeninger et al in reciting that the energy storage element is housed outside of the

5 implantable device that includes the circuitry for performing tasks. Leysieffer discusses the advantages of such an arrangement for replacing rechargeable batteries when they are no longer useful. One of ordinary skill in the art would have recognized the use of such an arrangement in the Weijand et al device for when its rechargeable battery needs replacing.

10 The applicant notes that claims 21 and 24 depend from claim 18, which has been amended as per the previous discussion. It is respectfully submitted that these amendments have obviated the present rejection.

CONCLUSION

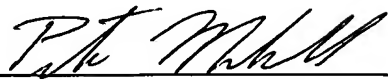
15 Applicant has amended the independent claims of the present application to recite a power output level not taught or suggested in the prior art of record. Applicant has also addressed the Examiner's various objections and rejections. Additionally, applicant has presented new claims (claims 38-43) in an earnest attempt to clarify his invention.

20 In light of the foregoing, applicant respectfully submits that the Examiner has failed to make a prima facie case of obviousness. In consideration of the arguments presented rebutting obviousness, and with the claims as currently amended, applicant believes that the application is in condition for allowance.

25 The applicant respectfully request reconsideration and that a timely Notice of Allowance be issued in this case. If, for any reason, the Patent Examiner believes that a telephone conference with applicant's agent might in any way facilitate the prosecution of this case, the Examiner is respectfully requested to call the undersigned.

30 To the extent necessary, please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-2753 and credit any excess fees to such deposit account. If necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made.

Respectfully submitted,
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